January 8, 1999

This document was submitted to EPA by a registrant in connection with EPA's evaluation of this chemical, and it is presented here exactly as submitted.

December 10, 1998

VALENT COMMENTS ON ACEPHATE DRAFT RE-REGISTRATION ELIGIBILITY DECISION (RED) PRELIMINARY RISK ASSESSMENTS-ATTACHMENT C

Dr. Angel Chiri
Chemical Review Manager
Special Review and Re-registration Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
Crystal Mall 2
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Arlington, VA. 22202

Dear Dr. Chiri:

Valent U.S.A. Corporation is pleased to provide comments on the draft Acephate Reregistration Eligibility Decision Science Chapters prepared by the Office of Pesticide Program's Health Effects Division (HED) and Environmental Fate and Effects Division.

We are taking this opportunity to advise the Agency of our concerns over extremely conservative risk assumptions and risk assessment procedures contained in the preliminary draft acephate science chapters. Our comments are by no means complete or final, however. In the interest of providing these comments in a timely manner, we are deferring additional, more detailed comments on additional issues and assumptions. We reserve the right to submit comments on these issues before or during the public comment period established for the corrected draft science chapters. Meanwhile, we request that this document be posted to the OPP Public Docket and to the OPP internet site along with the corrected draft science chapters.

The comments listed below are in response to assumptions found in the draft ACEPHATE HED Risk Assessment and Disciplinary Chapters for the Reregistration Eligibility Decision (RED) Document.

- Page 2, Acephate acute dietary risk assessment. It is not consistent to perform a tier 2 chronic risk analysis (anticipated residues and proportion of crop treated) and a tier 1 acute analysis (tolerance level residues and total crop treated). Valent will perform the suggested Monte Carlo analyses for acute dietary (food) exposure. Valent will advise the Agency as to when these analyses will be initiated.

- Page 3, Methamidophos dietary exposure analyses. The details of these analyses and the assumptions used are not available to Valent. Both chronic and acute analyses for methamidophos from acephate will be performed by Valent using assumptions and data consistent with the acephate analyses mentioned above. Valent will advise the Agency as to when these analyses will be initiated.

- Page 16, Because the figures are used later for various risk scenarios, a corresponding list of toxic versus exposure endpoints is needed for methamidophos in this document. It is important to note that the extra margin of exposure built into the RfD values and acceptable MOE values for methamidophos should only apply to infant and children sub-populations. The additional uncertainty factor has been added by the Agency because of hints of neurotoxicity in some toxicology studies, leading to the added requirement for a developmental neurotoxicity study.

- Pages 18-20, List of tolerances. The existing acephate tolerances (§180.108) that include both acephate and methamidophos are structured as a total residue with methamidophos not to exceed a designated amount. With the methamidophos portion of acephate tolerance removed to §180.315, the remaining acephate tolerances may be too large and need to be reevaluated.

- Page 22, Dietary risk analyses. Again the details and assumptions, particularly those for the food handling tolerance, are not explicit.

- Page 25, Identification of use scenarios. There are several identified use scenarios, that are unreasonable. For example, aerial application at 5 lb. ai/A - this use is for turf only, and while the labeling does not preclude aerial application, it does specify a minimum application volume of 5 gallons of water per 1000 ft^2. This requires nearly 220 gallons per acre. To treat the normal 350 acres in an 8 hour day would require more than 75,000 gallons of spray solution containing more than 2,300 lb. of ORTHENE 75. Clearly this is not a reasonable use scenario. The only chemigation application allowed is 1 lb. ai/A to cranberries. Cranberry bogs are small and they are not watered by giant center pivot irrigation systems covering 350 acres. The "forest" use is actually a very limited use on Christmas trees and pine seed orchards. An assumption of aerial applications to 800 acres is not reasonable.

- Page 79, There is a dermal adsorption study for acephate (Acc. No. 260617) and a supporting dermal metabolism study (Acc. No. 248018) both in rats that indicate that the dermal adsorption is approximately 10% per day. Using a dermal endpoint, the penetration factor is not relevant, however, assuming 100% is not correct.

The comments listed below are in response to statements and assumptions found in the draft ENVIRONMENTAL FATE AND EFFECTS DIVISION Reregistration Eligibility Decision Document Chapter for ACEPHATE that Valent considers scientific and/or judgmental errors. Our comments are as follows:

- At a number of points in the preliminary risk assessment, the Agency identifies methamidophos as "the major" or "the only" degradate of acephate. In fact, methamidophos is a relatively minor degradate, found at less than 10% of the applied dose in most environmental fate studies, and is certainly not the only one. It would be appropriate to say that methamidophos is a toxicologically significant degradate, but it is inaccurate and misleading to characterize it as "major".

- Water Resource Assessment, Valent agrees that acephate has a higher potential to contaminate surface water by runoff than to contaminate groundwater by leaching, Valent does not agree with "Acephate can be expected to move. . .". This statement implies a certainty: Apply acephate and contaminate surface water.

- Ecological Risk Characterization, "Acephate may induce aberrant migratory orientation and behavior..." This was the conclusion of a laboratory study conducted at high doses. Valent questions whether a laboratory study is applicable to birds found in production agricultural areas.

- Ecological Risk Characterization, "Fish may die indirectly as a result of acephate exposure." Valent would like to point out to the Agency that no mesocosm study has ever shown indirect effects which lead to fish mortality.

- Ecological Risk Characterization, "Yet, the involvement of acephate in mussel die-offs can not be fully discounted." This statement completely disregards the scientific evidence.

- Page 12, Terrestrial Exposure Assessment - Nongranular applications. In the table, "Broadleaf/forage plants and small insects" and "Fruits, pods, seeds and large insects" are not categories in either the Kenega nomograph (values under Predicted Maximum Residue) of the Fletcher reference (values under Predicted Mean Residue). Therefore, Valent does not know how the Agency obtained the values 135, 15, 45 and 7.

- Page 13, Effect of Acephate Degradate Methamidophos on Birds and Mammals. The statement, "...it was assumed that, upon application of acephate, there would be an instantaneous and complete conversion to methamidophos." is scientifically unsupported. Valent has performed numerous studies which the Agency has reviewed. Not one study has shown anything close to an instantaneous and complete conversion. In fact, the Agency's own fate assessment states that, under aerobic soil conditions, conversion of acephate to methamidophos ranges from a maximum of less than 10% of the applied dose,

to 23%. Thus, in Valent's viewpoint, the Agency is basing its risk estimates on a gross overestimate of methamidophos formation. Valent must cite it as an example of extreme conservatism when making assumptions.

- Pages 12, 13, 14 mention the model FATE. Valent has a model called FATE but it does not calculate concentrations or produce outputs as seen in Appendix F. Valent would like to ask the Agency for a complete reference of their FATE model. Is it available on the Web?

- Page 93, PRZM-EXAMS RESULTS. In the Acephate EFED RED report, the Agency stated that the parent/daughter algorithm in PRZM was used to estimate Methamidophos concentrations. Valent however, is unable to verify the Agency's numbers due to the fact the Agency does not list the specifics they used for this application (i.e. such as the Methamidophos formation rate and molar fraction converted to Methamidophos).

All questions or inquires that the Agency may have regarding Valent's response and comments on this subject can be directed to Mr. Brent Solomon at Valent's Washington D.C. office at (202) 872-4682 or to myself at (925) 256-2719.

Sincerely,

Mr. Joseph L. Powell
Project Manager
Registrations & Regulatory Affairs

cc: Dr. Wayne Carlson-Bayer Corporation
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